# **Complete Summary**

#### **GUIDELINE TITLE**

American Gastroenterological Association medical position statement: guidelines on osteoporosis in gastrointestinal diseases.

#### BIBLIOGRAPHIC SOURCE(S)

American Gastroenterological Association. American Gastroenterological Association medical position statement: guidelines on osteoporosis in gastrointestinal diseases. Gastroenterology 2003 Mar; 124(3): 791-4. [15 references] PubMed

## **COMPLETE SUMMARY CONTENT**

SCOPE

**CATEGORIES** 

METHODOLOGY - including Rating Scheme and Cost Analysis RECOMMENDATIONS EVIDENCE SUPPORTING THE RECOMMENDATIONS BENEFITS/HARMS OF IMPLEMENTING THE GUIDELINE RECOMMENDATIONS IMPLEMENTATION OF THE GUIDELINE INSTITUTE OF MEDICINE (IOM) NATIONAL HEALTHCARE QUALITY REPORT

IDENTIFYING INFORMATION AND AVAILABILITY

# **SCOPE**

#### DISEASE/CONDITION(S)

- Osteoporosis in inflammatory bowel disease (IBD)
- Osteoporosis in celiac disease
- Osteoporosis in postgastrectomy states

## **GUIDELINE CATEGORY**

Diagnosis Management Treatment

# CLINICAL SPECIALTY

Colon and Rectal Surgery Family Practice Gastroenterology Internal Medicine Pediatrics

#### INTENDED USERS

## Physicians

# GUIDELINE OBJECTIVE(S)

To provide recommendations for management of osteoporosis in patients with 3 common digestive disorders: inflammatory bowel disease, celiac disease, and postgastrectomy states

#### TARGET POPULATION

Adult and pediatric patients with osteoporosis with underlying gastrointestinal diseases including inflammatory bowel disease (IBD), celiac disease, and postgastrectomy states

#### INTERVENTIONS AND PRACTICES CONSIDERED

## Diagnosis

- 1. Dual-energy x-ray absorptiometry (DXA)
- 2. Measurement of serum calcium level corrected for albumin, complete blood count, total serum alkaline phosphatase (SAP), creatinine level, 25-(OH) vitamin D level, and testosterone level (in males)
- 3. Protein electrophoresis
- 4. Serum parathyroid hormone (PTH) measurement

# Treatment/Management

- 1. Patient education
- 2. Weight-bearing exercise, quitting smoking, avoiding excessive alcohol intake
- 3. Vitamin D and calcium supplementation
- 4. Keeping corticosteroid dosing to a minimum
- 5. Gluten-free diet
- 6. Estrogen therapy
- 7. Selective estrogen receptor modulator (SERM) raloxifene
- 8. Testosterone in males
- 9. Bisphosphonates such as alendronate, risedronate, and etidronate
- 10. Nasal or subcutaneous calcitonin

Note: Sodium fluoride and PTH were considered but not recommended.

#### MAJOR OUTCOMES CONSIDERED

- Prevalence of osteoporosis in inflammatory bowel disease (IBD), celiac disease, and postgastrectomy states
- Fracture prevalence and incidence in IBD, celiac disease, and postgastrectomy states
- Longitudinal changes in bone density in gastrointestinal disease
- Osteomalacia in gastrointestinal disease

#### METHODOLOGY

#### METHODS USED TO COLLECT/SELECT EVIDENCE

Hand-searches of Published Literature (Primary Sources) Hand-searches of Published Literature (Secondary Sources) Searches of Electronic Databases

#### DESCRIPTION OF METHODS USED TO COLLECT/SELECT THE EVIDENCE

The authors searched MEDLINE and the Institute for Scientific Information (ISI) Web of Science using general terms related to osteoporosis and metabolic bone disease ("osteopor-" OR "osteopen-" or "bone density" or "fractures" or "bone loss" or "bone mineral" or "bone metabolism" or DXA [TITLE] or DEXA [TITLE] or "bone densitometry") and combined these with specific terms for the relevant GI disorders ("inflammatory bowel disease" or "Crohn" or "Crohn's" or "ulcerative colitis;" "celiac disease" or "coeliac disease;" "postgastrectomy syndromes"[MESH] or "gastrectomy"[MESH] or "gastrectom-" or "postgastrectom-;" "liver/transplantation"[MAJR] or "liver diseases"[MAJR] or "liver transplantation"[MAJR]). We manually searched recently published reviews, references from retrieved articles, and expert committee reports for additional studies. Information related to the specific GI or hepatic disease was supplemented with background data on osteoporosis in the general population and non-GI disorders.

This review excludes skeletal disorders unrelated to osteoporosis, such as avascular necrosis, hepatitis C-associated osteosclerosis, and hypertrophic osteoarthropathy. Cystic fibrosis, although associated with significant bone demineralization and imbalance between bone formation and degradation, is not a primary GI disorder, and thus is not discussed further. Hepatobiliary rickets and liver disorders of infancy and early childhood (e.g., extrahepatic biliary atresia) are quite different from skeletal disorders that present in adults and older children and thus have also been excluded.

#### NUMBER OF SOURCE DOCUMENTS

Not stated

# METHODS USED TO ASSESS THE QUALITY AND STRENGTH OF THE EVIDENCE

Weighting According to a Rating Scheme (Scheme Given)

#### RATING SCHEME FOR THE STRENGTH OF THE EVIDENCE

The guideline authors graded evidence using guidelines adapted from the Practice Guidelines Committee of the American Association of the Study of Liver Diseases.

Quality of Evidence on Which a Recommendation is Based

Grade A: Homogeneous evidence from multiple well-designed randomized (therapeutic) or cohort (descriptive) controlled trials, each involving a number of participants to be of sufficient statistical power

Grade B: Evidence from at least 1 large well-designed clinical trial with or without randomization, from cohort or case-control analytic studies, or well-designed meta-analysis

Grade C: Evidence based on clinical experience, descriptive studies, or reports of expert committees

Grade D: Not rated

#### METHODS USED TO ANALYZE THE EVIDENCE

Meta-Analysis Systematic Review with Evidence Tables

#### DESCRIPTION OF THE METHODS USED TO ANALYZE THE EVIDENCE

Point estimates of osteoporosis prevalence and mean bone density were extracted and combined (weighted for patient numbers) to give pooled estimates. Combining data from studies with different designs does not take study heterogeneity into account, but can be taken to reflect general trends in the published data and is useful for approximating the overall magnitude of the impact of various GI disorders on bone metabolism. Pooling of data was site-specific but did combine related technologies, different vendors, reference ranges, and genders. The analysis did not demonstrate any difference in results restricted to a technology or vendor.

#### METHODS USED TO FORMULATE THE RECOMMENDATIONS

Not stated

#### RATING SCHEME FOR THE STRENGTH OF THE RECOMMENDATIONS

Not applicable

#### **COST ANALYSIS**

A formal cost analysis was not performed and published cost analyses were not reviewed.

## METHOD OF GUIDELINE VALIDATION

Peer Review

#### DESCRIPTION OF METHOD OF GUIDELINE VALIDATION

This paper was approved by the American Gastroenterological Association (AGA) Clinical Practice Committee on September 21, 2002 and by the AGA Governing Board on November 1, 2002.

## RECOMMENDATIONS

#### MAJOR RECOMMENDATIONS

Definitions for the strength of evidence (Grade A-D) are repeated at the end of the Major Recommendations.

The following steps outline a possible approach to managing osteoporosis in gastrointestinal (GI) disease:

- 1. All patients should receive education on the importance of lifestyle changes (e.g., engaging in regular weight-bearing exercise, quitting smoking, avoiding excessive alcohol intake), as well as vitamin D and calcium supplementation (level D evidence).
- 2. Dual energy x-ray absorptiometry (DXA) scans should be selectively ordered in inflammatory bowel disease (IBD) patients based on a thorough risk factor assessment (level D evidence).
- 3. DXA scans are likely unnecessary in patients with newly diagnosed uncomplicated pediatric celiac disease, but should be considered for adults with newly diagnosed celiac disease 1 year after initiation of a gluten-free diet, to allow for stabilization of bone density (level D evidence).
- 4. Patients who are at least 10 years postgastrectomy, especially postmenopausal females, males over age 50, and patients with low-trauma fractures should undergo DXA testing (level D evidence).
- 5. In patients with IBD and celiac disease, serum calcium level, corrected for albumin, should be measured at diagnosis. In IBD, celiac disease, and postgastrectomy states in which the patient is found to be osteoporotic or has a low-trauma fracture, screening for other causes of low bone density should be performed through a complete blood count, total SAP level, calcium level, creatinine level, 25-(OH) vitamin D level, protein electrophoresis, and testosterone level (in males) (level D evidence).
- 6. Serum measurements of parathyroid hormone (PTH) are unnecessary unless a patient is found to have an abnormal serum or urinary calcium level (level D evidence).
- 7. Implementation of a gluten-free diet in celiac disease and correction of nutritional deficiencies is necessary in all GI diseases (level A evidence).
- 8. Corticosteroid dosing in IBD should be kept to a minimum, and other immunomodulatory agents should be considered to help withdraw patients from corticosteroids once corticosteroid dependence becomes evident (level D evidence in IBD; level A evidence regarding fracture risk reduction by minimizing the corticosteroid dosage for other non-GI diseases).
- 9. Vitamin D and calcium supplementation should be given to those deemed to be at high risk for osteoporosis or with proven osteoporosis. Younger men and premenopausal women require 1000 mg/day of elemental calcium, whereas men and women over age 50 require up to 1500 mg/day. Vitamin D 400 to 800 IU/day is usually an adequate replacement dose in healthy individuals; it can be obtained from many multivitamin preparations (level D evidence in GI disease, level B evidence regarding nonvertebral and vertebral fracture risk

- reduction by optimizing calcium and vitamin D intake in older men and women).
- 10. Estrogen therapy has received U.S. Food and Drug Administration (FDA) approval for the prevention of osteoporosis in postmenopausal or hypogonadal premenopausal women, but must be balanced against the significant risks (level D evidence in GI disease, level A evidence for vertebral and nonvertebral fracture risk reduction in generally healthy postmenopausal women).
- 11. A selective estrogen receptor modulator (SERM) has been approved by the FDA for the prevention and treatment of osteoporosis in menopausal women (level D evidence in GI disease, level A evidence for vertebral fracture risk reduction in osteoporotic postmenopausal women). A bone disease specialist should participate in the decision to choose a SERM in patients with GI diseases.
- 12. Testosterone should be used to treat hypogonadism in males (level D evidence).
- 13. Bisphosphonates are FDA-approved for the prevention and treatment of osteoporosis in patients with known osteoporosis, patients with atraumatic fractures, and patients who cannot withdraw from corticosteroids after 3 months of use (level D evidence in GI disease, level A evidence regarding vertebral and nonvertebral fracture risk reduction in postmenopausal women).
- 14. Nasal or subcutaneous calcitonin can be considered as an alternative treatment approach when the preceding antiresorptive agents are contraindicated or poorly tolerated (level D evidence in GI disease, level A evidence regarding vertebral fracture risk reduction in postmenopausal women).
- 15. Fluoride is not recommended as treatment for osteoporosis associated with GI disease (level D evidence in GI disease, no consistent evidence for fracture risk reduction in postmenopausal women).

## Definitions:

Quality of Evidence on Which a Recommendation is Based

Grade A: Homogeneous evidence from multiple well-designed randomized (therapeutic) or cohort (descriptive) controlled trials, each involving a number of participants to be of sufficient statistical power

Grade B: Evidence from at least 1 large well-designed clinical trial with or without randomization, from cohort or case-control analytic studies, or well-designed meta-analysis

Grade C: Evidence based on clinical experience, descriptive studies, or reports of expert committees

Grade D: Not rated

## CLINICAL ALGORITHM(S)

An algorithm is provided in the technical review (see "Companion Documents" field) for management approach for osteoporosis in gastrointestinal disease

## EVIDENCE SUPPORTING THE RECOMMENDATIONS

# TYPE OF EVIDENCE SUPPORTING THE RECOMMENDATIONS

The type of supporting evidence is identified and graded for each recommendation (see "Major Recommendations").

# BENEFITS/HARMS OF IMPLEMENTING THE GUIDELINE RECOMMENDATIONS

#### POTENTIAL BENEFITS

Appropriate diagnosis and treatment of patients with osteoporosis and concomitant gastrointestinal disease

#### POTENTIAL HARMS

Side effects of medications used to treat osteoporosis

# IMPLEMENTATION OF THE GUIDELINE

#### DESCRIPTION OF IMPLEMENTATION STRATEGY

An implementation strategy was not provided.

# INSTITUTE OF MEDICINE (IOM) NATIONAL HEALTHCARE QUALITY REPORT CATEGORIES

**IOM CARE NEED** 

Getting Better Living with Illness

IOM DOMAIN

Effectiveness

# IDENTIFYING INFORMATION AND AVAILABILITY

#### BIBLIOGRAPHIC SOURCE(S)

American Gastroenterological Association. American Gastroenterological Association medical position statement: guidelines on osteoporosis in gastrointestinal diseases. Gastroenterology 2003 Mar; 124(3): 791-4. [15 references] <a href="PubMed">PubMed</a>

#### **ADAPTATION**

Not applicable: The guideline was not adapted from another source.

#### DATE RELEASED

2003 Mar

# GUIDELINE DEVELOPER(S)

American Gastroenterological Association - Medical Specialty Society

# SOURCE(S) OF FUNDING

American Gastroenterological Association

#### GUIDELINE COMMITTEE

American Gastroenterological Association Patient Care Committee

#### COMPOSITION OF GROUP THAT AUTHORED THE GUIDELINE

Not stated

#### FINANCIAL DISCLOSURES/CONFLICTS OF INTEREST

Dr. Charles Bernstein is supported in part by a Research Scientist Award from the Crohn's and Colitis Foundation of Canada and an Investigator Award from the Canadian Institutes of Health Research.

# **GUIDELINE STATUS**

This is the current release of the guideline.

According to the guideline developer, the Clinical Practice Committee meets 3 times a year to review all American Gastroenterological Association guidelines. This review includes new literature searches of electronic databases followed by expert committee review of new evidence that has emerged since the original publication date.

# GUIDELINE AVAILABILITY

Electronic copies: Available from the <u>American Gastroenterological Association</u> (AGA) <u>Gastroenterology journal Web site</u>.

Print copies: Available from the American Gastroenterological Association, 4930 Del Ray Avenue, Bethesda, MD 20814.

#### AVAILABILITY OF COMPANION DOCUMENTS

The following is available:

• Bernstein CN, Leslie WD, Leboff MS. AGA technical review on osteoporosis in gastrointestinal diseases. Gastroenterology 2003 Mar; 124(3):795-841.

Electronic copies: Available from the <u>American Gastroenterological Association</u> (AGA) Gastroenterology journal Web site.

Print copies: Available from the American Gastroenterological Association, 4930 Del Ray Avenue, Bethesda, MD 20814.

#### PATIENT RESOURCES

None available

# NGC STATUS

This summary was completed by ECRI on August 20, 2003.

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